

### **REMARKS**

Applicants thank the Examiner for the indication that claims 1, 11, 12 and 49-60 are free of prior art of record and are allowable.

Upon entry of this response, claims 1, 11, 12, 21-26, 36, 37 and 49-63 will be currently pending and under active examination in the above-identified patent application. Claims 27-35 and 38-51 have been canceled, claims 1, 11, 12, 21-24, 26, 36 and 49-61 have been amended, and claims 62 and 63 have been added to more clearly claim the invention described and enabled in the specification. In particular, claim 36 has been amended to recite that the host cell is an *in vitro* host cell. Claims 62 and 63 have been added so as to recite that the recombinant host cell is a eukaryotic cell or a human cell, respectively. Support for the amended and newly added claims is found in the specification as originally filed. No new matter is added.

#### **1. Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 27-30 and 36-37 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner contends that the specification, while being enabling for an isolated cell comprising the DNA of claims of 1, 21 and 22 *in vitro*, does not allegedly provide reasonable enablement wherein the cell is present *in vivo*.

In response, claims 27-30 have been cancelled, obviating the rejection with respect to those claims. With respect to claim 36 and claims dependent therefrom, Applicants assert that one skilled in the art would understand that a recombinant host cell is not a cell in an organism, but rather a cell *in vitro*. Applicants submit that the term recombinant host cell is not used to describe cells in organisms. Nevertheless, Applicants have amended claim 36 to recite an *in vitro* recombinant cell so that it is clear that the recombinant host cell is not in an organism.

In view of the above, it is submitted that the rejection has been obviated. Thus, Applicants respectfully request that this Section 112 rejection be withdrawn.

## **2. Rejection Under 35 U.S.C. § 102**

**A.** Claim 21 is rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by Shepard *et al.* (U.S. Patent No. 5,710,255, issued January 20, 1998), hereafter "Shepard". According to the Examiner, Shepard discloses a nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO:37.

The legal standard for anticipation is that in order for a reference to anticipate a claim, each and every element of the claim must be disclosed in that one reference.

*Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1985).

"Anticipation under Section 102 can be found only if a reference shows exactly what is claimed . . ." *Structural Rubber Prod. Co. v. Park Rubber Co.*, 749 F.2d 707 (Fed. Cir. 1984).

Applicants respectfully disagree with the Examiner's rejection for the reasons set forth below. As explained in the specification on page 75, lines 5 and 6, SEQ ID NO:37 sets forth the amino acid sequence of a modified retinoblastoma protein, which is modified by a deletion of amino acids 1-147 as compared to the wild-type retinoblastoma protein. SEQ ID NO:36 sets forth a nucleotide sequence that encodes this particular modified retinoblastoma protein. Shepard discloses a cDNA nucleotide sequence encoding the wild-type retinoblastoma tumor suppressor protein, p110<sup>RB</sup>, identified in Shepard as SEQ ID NO:2 (see third column line 2). Shepard does not teach, much less, suggest the modified protein of SEQ ID NO:37, nor its encoding nucleotide sequence. It appears that the Examiner has mistakenly taken the homology results between a portion of full length wild-type retinoblastoma protein corresponding to the sequence of SEQ ID NO:37 and the claimed modified protein, as evidence that Shepard did disclose the claimed sequence. A portion of the sequence found in Shepard is identical to SEQ ID NO:37, but the claimed sequence depicted in SEQ ID NO:37 and the sequence disclosed in Shepard are not identical. Thus, Shepard does not anticipate the claimed subject matter or SEQ ID NO:37.

**B.** Claims 21-30, 36, 37 and 61 are rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Xu *et al.* (U.S. Patent No. 5,496,731, issued March 5 1996). The Examiner alleges that, similarly to Shepard, that Xu *et al.* disclose the nucleotide and amino acid sequences of SEQ ID NOS:36 and 37. Preliminarily, Applicants note that Xu *et al.* also qualifies as prior art under 35 U.S.C. §102(e).

Applicants disagree with this rejection and point out that Xu *et al.* do not disclose a modified retinoblastoma protein having a deletion of amino acids 1-147 as compared to the wild type retinoblastoma tumor suppressor protein. Xu *et al.* disclose two

proteins, p110<sup>RB</sup>, as well as a second in-frame AUG codon-initiated retinoblastoma suppressor protein, p94<sup>RB</sup> (see column 3, lines 1-21; column 9, lines 55-66; and column 10 lines 37-53). Since a deletion of the 5' most 147 amino acids of the wild-type retinoblastoma tumor suppressor protein is not disclosed by Xu *et al.*, Xu *et al.* do not disclose exactly what is claimed, and thus, the reference is not anticipatory.

C. Claims 21-30, 36, 37 and 61 are rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Lee *et al.* (WO 90/05180), hereafter "Lee". As in the above Section 102 rejections, the Examiner alleges that the cited reference discloses the amino acid sequence of SEQ ID NO:37 and its encoding nucleic acid depicted in SEQ ID NO:36.

Applicants respectfully disagree. Lee discloses the identical cDNA nucleotide sequence encoding the wild-type retinoblastoma tumor suppressor protein, p110<sup>RB</sup>, as disclosed in Shepard and Xu *et al.* Lee does not disclose a modified protein having a deletion of amino acids 1-147 as compared to wild-type. Thus, Lee does not disclose exactly what is claimed, and thus, is not anticipatory.

In view of the foregoing, Applicants submit that the Examiner's Section 102 rejections are in error, and Applicants respectfully request their withdrawal.

### **CONCLUSION**

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the present application. Claims 1, 11, 12, 21-26, 36, 37, and 49-63 fully meet all statutory requirements for patentability and enablement. Withdrawal of the Examiner's objection and rejections is respectfully requested.

Respectfully submitted,

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Enclosures